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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,180	01/14/2004	Robert L. Stout	31645-DIVI	4165

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,180	<b>Applicant(s)</b> STOUT ET AL.	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/20&amp;23/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

1. The Art Unit Location to which your application has been assigned at the USPTO is Art Unit 1655. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.
2. To facilitate expeditious prosecution of this application and prevent any potential loss of documents during communication with this office, Examiner suggests that applicants write the application number and attorney docket number in the header for each page of any future communication with this office.

## **Claims Status**

3. Claim 1 is pending and is examined on merits.

## **Priority**

4. Applicants' claim for domestic priority under 35 U.S.C. § 121 to Non-Provisional U.S. Application 10/037,772, filed 9 November 2001 is acknowledged.

## **Information Disclosure Statement**

5. Applicants' Information Disclosure Statement (i.e., IDS) filed 20 February 2004 and Supplementary Information Disclosure filed 23 February 2004 have been made of record and considered.

## **Objection To Claims – Minor Informalities**

6. Claim 1 is objected to because of the following informalities:
  - The recitation, "enzymes " at Line 5, renders Claim 1 unclear because only one enzyme is claimed in the preamble of Claim 1.

Appropriate correction is required.

## **Claim Rejections - 35 USC § 102**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

8. Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by Peiguo et al (Laboratory News Yale University School of Medicine, 1996, Volume 38, Number 1, Pages1-2, <http://info.med.yale.edu/labmed/labnews/feb196b.html>).

Claim 1 recites a method to measure the activity of an enzyme via bringing together a sample comprising said enzyme, a known quantity of a substrate selected for said enzyme and defining said measured activity of said enzyme on said substrate as the "standard enzyme activity".

Peiguo et al. teach a method to measure angiotensin converting enzyme (i.e., ACE) activity. Said method is a standard enzyme activity measurement method since in said method serum samples from patients are brought together with a specific ACE substrate, e.g., N- [3-(2-furylacrylyl)]-L-phenylalanylglycylglycine (i.e., FAPGG) and enzyme activity is measured spectrophotometrically as release of N- [3-(2-furylacrylyl)]-L-phenylalanine from FAPGG (Page 1, Paragraph 1). The reference describes the same method applying same components (i.e., sample containing an enzyme and a substrate specific for ACE) as are recited in the claimed invention.

Therefore, the reference is deemed to anticipate the cited claims.

9. Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by Harjanne (Clinical Chemistry, 1984, Volume 30, Number 6, Pages 9-1-902).

Claim 1 recites a method to measure the activity of an enzyme via bringing together a sample comprising said enzyme, a known quantity of a substrate selected for said enzyme and defining said measured activity of said enzyme on said substrate as the "standard enzyme activity".

Harjanne teaches a method to measure angiotensin converting enzyme (i.e., ACE) activity. Said method is a standard enzyme activity measurement method since in said method serum samples from patients are brought together with a specific ACE substrate, e.g., 3-(2-furylacrylyl)-L-phenylalanylglycylglycine (i.e., FAPGG) and enzyme activity is measured in a compact clinical analyzer (Page 301, Column 2, see section on Materials and methods). The reference describes the same method applying same components (i.e., sample containing an enzyme and a substrate specific for ACE) as are recited in the claimed invention.

Therefore, the reference is deemed to anticipate the cited claims.

10. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

- Morin et al., U.S. Patent 3,899,397. Issued 12 August 1975. Method to assay glutamic oxalacetic acid in serum.
- Madapally et al., U.S. Patent 4,242,446. Issued 30 December 1980. Assay for a dehydrogenase enzyme in a biological fluid.

- Ryan et al., U.S. Patent 4,276,378. Issued 30 Jun3 1981. A method to measure angiotensis converting enzyme in clinical materials.
- Mallia, U.S. Patent 5,527,688. Issued 18 June 1996. Rapid assay for protein kinase.
- Fridland et al., U.S. Patent 5, 576, 177. Issued 19 November 12996. Bioassay for reverse transcriptase inhibitors.
- Zebata, U.S. Patent 6,159,681. Issued 12 December 2000. Biological materials analyzed for the activity of ACE.

### ***Claim Rejections 35 U.S.C. §112:***

11. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

12. Claim 1 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- Phrases, "standard enzyme activity" or "enzyme's standard activity" render claim 1 vague, unclear and incomprehensible because the metes and bounds for said phrases are not explicitly claimed in the claim language. Do these phrases refer to a particular enzyme or group of enzymes or a family of enzymes, or to any enzyme? Said phrases are also unclear because the parameters to measure said enzyme activity are not explicitly claimed. Consequently, what might be construed "standard" under one set of parameters may not be standard activity under another set of parameters. Applicants need to clearly define the metes and bounds for the phrases, "standard enzyme activity" and "enzyme's standard activity".
- The recitation, "selected" renders the claim 1 vague and indefinite because without reciting what is being selected, the recitation "selected" is similar to the word "preferably" and is indefinite. It is not clear how one can determine with clarity and accuracy when the "selection" is to be exercised and what are the metes and bounds of said recitation.

### **Conclusion**

13. For reasons aforementioned, no Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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PRIMARY EXAMINER  
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April 26, 2006